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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/921,060	08/29/1997	DARRELL R. ANDERSON	012712-432	9119

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/921,060	Anderson et al.
Examiner	**Art Unit**
Ron Schwadron	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ~~4/24/2001~~ 4/24/2001, 8/8/2001, 10/2/2001 and 11/20/2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 11-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 11-13 and 16-20 is/are rejected.

7) ☒ Claim(s) 14 and 15 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1. Claims 11-20 are under consideration. Claim 12 has been amended. Claims 16-20 are newly added.

RESPONSE TO APPLICANTS ARGUMENTS

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because It does not identify the citizenship of each inventor. The citizenship of Inventors Hanna and Newman has been omitted.

Applicant has indicated that a new oath will be provided upon indication of allowance.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is indefinite in the recitation of "administered four four weeks". A preferred substitution is "administered for four weeks". Claim 19 depends on claim 11 and is therefore a duplicate of claim 14. Claim 20 depends on claim 19 and is therefore a duplicate of claim 15.

5. Regarding priority for the claimed invention and the application of prior art, the claimed invention is now receiving priority to parent application 08/149099.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11-13,16-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Press et al. (Blood) in view of Hellstrom et al. (WO 92/07466) and Robinson et al. (US Patent 5,500,362)for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Press et al. teach the use of a murine anti-CD20 antibody (see abstract) for the treatment of B cell lymphoma. Press et al. teach that therapeutic anti-CD20 antibody was administered to patients that had received at least one chemotherapeutic agent(see page 586, column 1). Press et al. teach the use of murine anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see Figure 2) wherein the dosage used is encompassed by the range recited in claim 11 or 16 (see Figure 2). Press et al. does not teach that the method uses a chimeric antibody with the functional property recited in the claims. While the murine antibody taught by Press et al. has the functional properties recited in claim 11, Robinson et al. teach that it would be expected that a chimeric anti-CD20 would have greater lytic activity in vivo compared to the murine antibody from which it is derived, because the chimeric antibody would possess increased ADCC and CDC (see column 20). Hellstrom et al. teach that chimeric antibodies have increased immune function because they contain human Fc (see page 13). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Press et al. teaches the use of antiCD20 antibody to treat B cell lymphoma, while Hellstrom et al. teach chimeric monoclonal antibody treatment in

combination with chemotherapeutic agents can be used to treat cancer and both Hellstrom et al. and Robinson et al. teach the use of chimeric antiCD20 antibody to treat B cell lymphoma and the advantages of using such antibodies. One of ordinary skill in the art would have been motivated to do the aforementioned because Hellstrom et al. teach the use of chimeric antibodies in combination with chemotherapy (see page 7) and Robinson et al. teach the use of chimeric anti-CD20 antibody for the treatment of B cell lymphoma (see column 20). A routineer would have determined the particular time points for administering the antibody as recited in claims by routine experimentation.

Regarding applicants comments, Press et al. (Blood) teach the use of murine anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see Figure 2) wherein the dosage used is encompassed by the range recited in claim 11 or 16 (see Figure 2). Press et al. does not teach that the method uses a chimeric antibody with the dose recited in the claims. While the murine antibody taught by Press et al. has the functional properties recited in claim 11, Robinson et al. teach that it would be expected that a chimeric anti-CD20 would have greater lytic activity in vivo compared to the murine antibody from which it is derived, because the chimeric antibody would possess increased ADCC and CDC (see column 20). Hellstrom et al. teach that chimeric antibodies have increased immune function because they contain human Fc (see page 13). Regarding applicants comments about the Anderson declaration, said declaration is drawn to the C2B8 antibody. Said antibody is not recited in the claims under consideration. The scope of the alleged unexpected results in the Anderson declaration is not commensurate with the scope of the claimed invention. Furthermore, Press et al. (Blood) teach the use of murine anti-CD20 antibody wherein said antibody depletes virtually all peripheral B cells within 24 hours(see Figure 2) wherein the dosage used (10 mg/$\mathbf{m}^2$) is encompassed by the dosage (eg. about .4 mg/kg) recited in claim 11 (see Figure 2). The dosage used by Press et al. is 10 mg/$\mathbf{m}^2$ wherein 10 mg are administered per square meter of patient. For the average 75 kg/ 2 square meter human, the 10 mg/m^2 dosage is equivalent to approximately .27mg/kg which is within the range encompassed by "about .4 mg/kg" recited in claim 11. While the murine antibody taught by Press et al. has the functional properties recited in claim 11 or 16, Robinson et al. teach that it would be expected that a chimeric anti-CD20 would have even greater lytic activity in vivo compared to the murine antibody from which it is derived, because of increased ADCC and CDC. Regarding claims 11 and 16, said claims do not even recite a dosage of antibody that is administered, they merely recite a functional property of the antibody. Regarding the 1000 or 2000 mg dosage of murine

antibody disclosed by Press et al., said dosage is the total dosage of antibody used (not 1000mg/kg, but 1000mg/ patient). Said dosage only actually constitutes about 13mg/kg (1000 mg) or 26 mg/kg (2000mg) for the hypothetical 75 kg patient. In view of the teachings of Hellstrom et al. and Robinson et al., that a chimeric anti-CD20 would have even greater lytic activity in vivo compared to the murine antibody from which it is derived, because of increased ADCC and CDC, it would have been obvious that doses smaller than 13mg/kg or 26mg/kg of the chimeric antibody could have been used in vivo. Furthermore, the dosage of 13mg/kg (1000 mg) or 26 mg/kg is actually encompassed by that recited in claim 16.

10. Claims 14,15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Regarding applicants comments about an interference, an interference requires an allowed claim(s).

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-

4242.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644
February 11, 2002